IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TAMMY PIZZITOLA, *Plaintiff*,	§	
v.	§	CIVIL ACTION NO. 4:20-CV-02256
ETHICON, INC. and JOHNSON & JOHNSON, *Defendants*.	§	

ORDER

Before the Court is the Motion to Exclude Certain Opinions and Testimony of Prof. Dr. Med. Uwe Klinge filed by Defendants Ethicon, Inc. and Johnson & Johnson. (Doc. No. 164). Plaintiff Tammy Pizzitola has filed a response in opposition and Defendants have replied. (Doc. Nos. 166, 171). The Court hereby **grants** the motion.

I. Legal Standard

Defendants' motion was filed primarily under the principles set in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). *Daubert*'s holdings have been summarized as follows:

> Reliable testimony must be grounded in the methods and procedures of science and signify something beyond "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786. The inferences or assertions drawn by the expert must be derived by the scientific method. *Id.* In essence, the court must determine whether the expert's work product amounts to "'good science.'" *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("Daubert II") (quoting *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786). In *Daubert*, the Supreme Court outlined factors relevant to the reliability prong, including: (1) whether the theory can be and has been tested; (2) whether it has been subjected to peer review; (3) the known or potential rate of error; and (4) whether the theory or methodology employed is generally accepted in the relevant scientific community. *Daubert*, 509 U.S. at 593–94, 113 S.Ct. 2786. The Supreme Court emphasized the "flexible" nature of this inquiry. *Id.* at 594, 113 S.Ct. 2786. As later confirmed in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999): "*Daubert*'s list of specific factors neither

> necessarily nor exclusively applies to all experts or in every case. Rather the law grants a district court the same broad latitude when it decides how to determine reliability as [the court] enjoys in respect to its ultimate reliability determination." *Id.* at 141–42, 119 S.Ct. 1167.

Abarca v. Franklin Cty. Water Dist., 761 F. Supp. 2d 1007, 1021 (E.D. Cal. 2011).

While *Daubert* attacks usually focus on a witness' reliability, some courts have also included an attack on a witness' qualification (or lack thereof) under the *Daubert* umbrella. Defendants' motion has the elements of both. Additionally, the Court finds that some of the objections fall more appropriately under the umbrella of relevance rather than reliability.

II. Prior *Daubert* Rulings of the MDL Court

At the onset, the Court notes that Defendants assert in their motion that both sides have agreed to be bound by the *Daubert* rulings previously made by the MDL Court. (Doc. No. 159). While the parties stipulated to be bound by those rulings for purposes of the trial in this case, each side apparently reserved the right to appeal those rulings at the appropriate time post-judgment. This, of course, puts this Court in a somewhat interesting position. It can reject this stipulation, or it can accept such stipulation and then later be second-guessed on appeal for a ruling it did not make. While this Court questions whether one can appeal the ultimate results of a stipulation that a party voluntarily entered, it accepts the parties' stipulation.

That being the case, there are various objections contained in Defendants' motion that this Court need not address, as they were already addressed in the MDL and were repeated by the Defendants here only as a means of preserving the Defendants' objection to the ruling.

III. Defendants' Motion

Dr. Klinge is a general surgeon who has extensive experience in performing abdominal, hernia, and gastrointestinal surgery. He is widely published and has consulted for many entities, including Ethicon. With the exception of his opinions on the state of mind of the Defendants'

employees (a topic already addressed and excluded by the MDL Court), Defendants do not really attack his qualifications.

What they do seek is to limit certain testimony. Defendants seek to limit Dr. Klinge's testimony such that he should not be allowed to testify about:

1. The Prolift +M;

2. The availability of polyvinylidene fluoride ("PVDF") mesh as a safer and available alternative design in 2009;

3. The availability of Ethicon's Ultrapro mesh as a safer and available alternative design in 2009; and

4. PVDF as a safer and available alternative because his opinion is not based upon reliable sources such as testing or scientific literature.

This last complaint listed above has already been addressed and denied by the MDL Court. Consequently, this Court need not address it in that context; however, it cautions that this ruling may affect the admissibility of that testimony.

As noted above, the MDL Court also found that Dr. Klinge could not opine as to the state of mind of the Defendants' employees (based upon the Defendants' documents) and that he could not opine in the form of narrative summaries of the Defendants' documents. The MDL Court specifically reserved for the trial courts whether Ultrapro was a safer and available alternative product.

IV. Prolift +M Testimony

The first issue is the simplest. Plaintiff in response to the Defendants' motion, concedes that she will not solicit testimony on the topic of Prolift +M. (Doc. No. 156 at 5). Dr. Klinge is hereby precluded from testifying in any fashion about the Prolift +M product.

V. Alternative Safer Designs—PVDF Mesh and Ultrapro Mesh

Plaintiff and Defendants disagree over whether Dr. Klinge's testimony concerning the availability of safe alternatives existed in October 2009 when Plaintiff had the TVT-O implanted. Most of the briefing centers around the reliability of Dr. Klinge's opinions. Plaintiff concentrates on the breadth of Dr. Klinge's experience and work in this area. Additionally, the Court has been referred to the MDL rulings, in which the objections to the reliability concerning PVDF has been denied, and reminded that the parties have agreed to abide by those rulings. Defendants concentrate on the lack of testing of these proposed alternatives and the lack of reliable published, peer-reviewed data upon which the doctor can base his opinion.

The Court finds that the answer to this controversy turns less on a *Daubert* analysis and more on an analysis of Federal Rule of Evidence 401. Fed. R. Evid. 401. Rule 401, of course, is the initial rule of the Article IV of the Federal Rules of Evidence that governs "Relevance and Its Limits." *Id.* That rule sets out the general standard that evidence is relevant if it tends "to make a fact more or less probable" and that "fact is of consequence in determining the action." *Id.* The Court finds the testimony in question is not relevant because the "fact" it tends to prove is not of consequence.

The elements of a design defect claim are well-established in Texas. A plaintiff must prove that: (1) the product was defectively designed (so as to be unreasonably dangerous); (2) a safer alternative design existed; and (3) the defect caused the injuries. *Timpte Industries, Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). These same three elements have been applied consistently in medical device cases. *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 765–66 (5th Cir. 2018). The alternative design not only has to

be safer, but it must be economically and technologically feasible and available. *Hernandez v. Tokai Corp.*, 2 S.W.3d 251 (Tex. 1999).

In the instant case, the Defendants contend, and the Plaintiff does not contest, that neither PVDF nor Ultrapro were approved by the FDA at the time of her surgery. Since they were not FDA approved, it was not feasible for either to be used by Plaintiff's physicians. The fact that they may have been in development and might eventually be on the market for use in humans is not relevant or material to prove a design defect. The Court, therefore, grants Defendants' motion to exclude.[1]

VI. Conclusion

Defendants' Motion to Exclude Prof. Dr. med. Uwe Klinge is **granted**. The stipulation concerning the prior rulings of the MDL Court is adopted. The motion to exclude any testimony by Dr. Klinge concerning Prolift +M is **granted**. The motion to exclude as it pertains to Dr. Klinge's testimony concerning safer alternatives in the design defect context is also **granted**.

SIGNED at Houston, Texas this 7th day of October, 2022.

Andrew S. Hanen
United States District Judge

[1] This Court's ruling is obviously based upon Texas' law on design defects. It is limited to that cause of action. The relevance, if any, of this testimony to other claims or defenses is not before the Court.